Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

9/503d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 2956435

July 10, 2001

Luis M. Oliveira
Oliveira Dairy
28399 Husman Road
Gustine, California 95322

WARNING LETTER

Dear Mr. Oliveira:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on June 12 and 13, 2001 by the Food and Drug Administration (FDA) have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On April 10, 2001, you consigned a cow, identified with back tag number 93 DQ 9071 (USDA laboratory report number 406758), for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of the drug sulfamethazine in the liver at 34.40 parts per million (ppm), and in the muscle at 39.80 ppm. A tolerance has been established for residues of sulfamethazine in the edible tissues of cattle at 00.10 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling or your veterinarian's prescription labeling.

4. You lack an adequate system for assuring that animals have been treated only with drugs that have been approved for use in their class of animal or species.

5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

The Sustain III brand sulfamethazine boluses that your establishment uses to treat lactating cows, are adulterated under Section 501(a)(5) of the Act in that they are new animal drugs within the meaning of Section 201(v) and are unsafe within the meaning of Section 512(a)(1)(B) of the Act, since they are not being used in conformance with approved labeling. Sustain III labeling specifically states, "Do not use in female dairy cattle 20 months of age or older." Your practice of using Sustain III in cattle older than 20 months of age, coupled with a failure to comply with the withdrawal time, is likely the cause of the sulfamethazine residues in the cow you consigned for slaughter.

Your practice of injecting your dairy cows with Agripharm Oxy-Mycin 100 brand oxytetracycline hydrochloride is not in conformance with approved labeling. Labeling for Oxy-Mycin 100 specifically states it is not to be used to treat lactating dairy cattle. The use of oxytetracycline to treat lactating cows will likely cause illegal residues in animals you consign for slaughter.

Failure to comply with the label instructions on drugs you use to treat your cows and calves presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act.

The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Warren E. Savary, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

Dennis K. Linsley
District Director

cc: [redacted]